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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,140	01/08/2007	Philip Wilson Howard	065435-9083-US00	4288
23510 7590 07/06/2009 MICHAEL BEST & FRIEDRICH LLP ONE SOUTH PINCKNEY STREET P O BOX 1806 MADISON, WI 53701			EXAMINER RODRIGUEZ-GARCIA, VALERIE	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			07/06/2009 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/591,140

**Applicant(s)**

HOWARD ET AL.

**Examiner**

VALERIE RODRIGUEZ-GARCIA

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04/29/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 10-21 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/20/2006, 03/10/2009, 06/04/2009.

### DETAILED ACTION

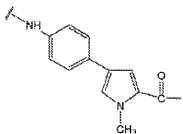
Claims 22, 24 and 26 have been canceled. Therefore, claims 1-21, 23 and 25 are currently pending in this application.

#### *Priority*

This application is a 371 of PCT/GB2005/00752, filed on March 1, 2005, which claims priority benefit of foreign application GB 0404574.6, filed on March 1, 2004. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### *Response to Restriction*

Applicant's election **without traverse** of Group II, claims 6-9 and 23, drawn to products represented by formula (II) ~~-CO-A-B-NH-~~ (II) and elected species fragment



derived from compound 32 (p. 59) , in the reply filed on 04/29/2009 is acknowledged.

Therefore, claims 1-5, 10-21 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations.

Elected Group II is being examined according to M.P.E.P. § 803.02. The claims within elected Group II have been examined to the extent that they are readable on the elected species above. Since prior art was found on the elected species, the examination stopped and art has been applied against the claims. Note, M.P.E.P. § 803.02. The subject matter of the search (inclusive of the elected species above) is as follows:

**The scope of the elected invention for search and examination:**

Products of Formula (II), ~~-CO-A-B-NH-~~ (II), depicted in claim 6, wherein: **A is optionally substituted pyrrole and B is optionally substituted phenyl**, classified in class 548/530. As a result of the election and the corresponding scope of the invention identified supra, claims 1-5, 10-21 and 25 and the remaining subject matter of claims 6-9 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as morpholine, triazole, pyrimidin, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. classification system, i.e. class 544 subclass 106(+) (morpholine), class 540 subclass 215(+) (triazoles), 544 subclass 224(+) pyrimidines, etc. Therefore, the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly. A reference which anticipates the elected subject matter would not render obvious the withdrawn subject matter. In addition, the fields of search are not co-extensive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The claims embraced by the above scope of elected invention for search and examination are claims 6-9 and 23.

*Pursuant to amendment claims 1-21, 23 and 25 are currently pending, claims 1-5, 10-21 and 25 are withdrawn and claims 6-9 and 23 are the subject of this office action. This is the First Action on the merits of the claims.*

*Note:* The elected species is not allowable. See rejections below.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6-9 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6 and 9 the term "comprising" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "comprising"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). In the instant application the claim scope is drawn to a product (a polyamido moiety and a compound). "A compound comprising" and "a polyamido moiety

comprising" allow for inclusion of indefinite number of members or compounds. A person of ordinary skill in the art will not understand what other adduct components are present or what other agents or molecules are included or excluded by the claim language. It is suggested that Applicants replace "comprising" with "consisting of".

In claim 8 the recitation "A and B are independently selected from phenylene, and arylene groups derived from C5 heteroaryl groups" renders the claim(s) indefinite. It is not clear what "phenylene and arylene groups derived from C5 heteroaryl" means. Phenylene is a substituted benzene (C<sub>6</sub>), which the specification also refers to as "carboaryl group" (see page 5). How can a phenylene be derived from a heteroaryl group, as claimed? A heteroaryl group contains heteroatoms within the ring. Phenylene and heteroaryl are different groups. Also, an arylene group, as defined in page 5 of the specification, pertains to "carboaryl groups such as phenylene" and "heteroarylene groups". However, claim 8 discloses arylene is a different group from phenylene or heteroarylene. This is not the definition the specification gives. What is "arylene derived from C5 heteroaryl groups"? It is not therefore, possible to ascertain the definition of A and B in claim 8. Appropriate correction is required.

In claim 7 it is not understood what the letters (G) and (K) mean. These are not recited in the formula of claim 7, neither in claim 6, which claim 7 depends on. Applicants are suggested to delete (G) and (K) from claim 7.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

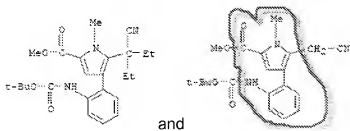
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 6-9 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Dupont *et al.* (Tetrahedron Lett. 2000, 41 (31); p. 5853-5856).

The instant claims recite "a polyamido moiety". The term moiety means a segment or portion or a specific fragment of a molecule. Therefore, "a polyamido moiety" means "a fragment or segment of a polyamido". The claims are thus drawn to a fragment, not to a polyamido, as applicants further evidenced by their species election. Because the claims are drawn to a fragment (composition of matter), it does not matter where the fragment comes from or where it will be used. Therefore, claim 6 only requires the presence of the segment of formula (II) anywhere. Claim 9 recites "a compound comprising", wherein the only limitations disclosed are those of claim 6. "A compound comprising" of claim 9 is being interpreted as a compound comprising the moiety of claim 6, which is anything that contains the moiety of formula (II).

Dupont *et al.* disclose at least the compounds



, which contain the moiety-CO-A-B-NH- of the instant claims, wherein A is substituted pyrrol and B is phenyl. See Table 1 in page 5854. A pharmaceutical composition with an acceptable carrier or diluent is the compound dissolved in DME-water.



***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

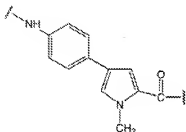
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 6-9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0138269.

The instant claims recite "a polyamido moiety". The term moiety means a segment or portion or a specific fragment of a molecule. Therefore, "a polyamido moiety" means "a fragment or segment of a polyamido". The claims are thus drawn to a fragment, not to a polyamido, as applicants further evidenced by their species election. Because the claims are drawn to a fragment (composition of matter), it does not matter where the fragment comes from or where it will be used. Therefore, claim 6 only requires the presence of the segment of formula (II) anywhere. Claim 9 recites "a compound comprising", wherein the only limitations disclosed are those of claim 6. "A compound

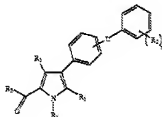
comprising" of claim 9 is being interpreted as a compound comprising the moiety of claim 6, which is anything that contains the moiety of formula (II).

Applicants claim a polyamido moiety comprising the elected species



Determination of the scope and content of the prior art (MPEP §2141.01)

US 2004/0138269 claims compounds with structurally similar moieties. See claim 5 of



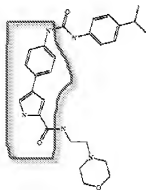
the prior art for the following formula:

, wherein R<sub>1</sub>, R<sub>3</sub> and

R<sub>4</sub> can be hydrogen or alkyl, R<sub>5</sub> can be -NR<sub>6</sub>R<sub>7</sub> and L can be -NR<sub>8</sub>C(O)-. More

specifically, one of the disclosed species is compound Example 42 in page 28 [0409].

[0409]



The prior art compounds are useful as kinase inhibitors.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The pyrrole-phenyl moiety of the compounds of the reference (seen in red above) differs from Applicant's elected species in that it has a hydrogen atom in the nitrogen of the pyrrole ring instead of a methyl. Therefore, the claimed moiety and the prior art moieties are homologues.

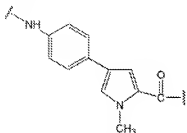
Finding of prima facie obviousness---rational and motivation (MPEP §2142-2413)

First, the claims of the prior art US 2004/0138269 disclose alkyl as substituent in the nitrogen of the pyrrole ring. In addition, it has been held that members of a homologous series are not patentable absent a showing of unexpected properties. *In re Henze*, 85 USPQ 261 (1950). To those skilled in the art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. The instant claimed compounds would have been obvious, because one skilled in the art would have been motivated to prepare homologues of the compounds taught in the reference with the expectation of obtaining compounds which could be useful as kinase inhibitors. A person of ordinary skill in the art would enjoy a reasonable expectation of success moreover in view of the reference US 2004/0138269 teachings.

8. Claims 6-9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0138269 in view of Wolff, M.E. *Burger's Medicinal Chemistry 4<sup>th</sup> Ed. Part I*, Wiley: New York, **1979**, 336-337.

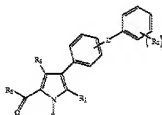
Art Unit: 1626

Applicants claim a polyamido moiety comprising the elected species:



Determination of the scope and content of the prior art (MPEP §2141.01)

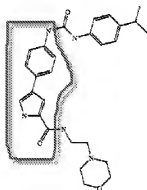
US 2004/0138269 claims compounds with structurally similar moieties. See claim 5 of



the prior art for the following formula:

, wherein R1, R3 and R4 can be hydrogen or alkyl, R5 can be -NR6R7 and L can be -NR8C(O)-. More specifically, one of the disclosed species is compound Example 42 in page 28 [0409].

[0409]



The prior art compounds are useful as kinase inhibitors. Pharmaceutical compositions comprising a carrier or excipient can be found in page 5, paragraphs [0113, 0114 and 0115].

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The pyrrole-phenyl moiety of the compounds of the reference (seen in red above) differs from Applicant's elected species in that it has a hydrogen atom in the nitrogen of

the pyrrole ring instead of a methyl. Therefore, the claimed moiety and the prior art moieties are homologues.

*Finding of prima facie obviousness---rational and motivation (MPEP §2142-2413)*

First, the claims of the prior art US 2004/0138269 disclose alkyl as substituent in the nitrogen of the pyrrole ring. In addition, Wolff teaches that the addition of alkyl groups to active pharmacological agents often improves activity and bioavailability by increasing lipophilicity (see the examples in Table 8.2, p. 337 of a local anesthetic SAR). As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compounds such as those disclosed in US 2004/0138269, with methyl for a hydrogen, as suggested by Wolff, to achieve better bioavailability. A person of ordinary skill would enjoy a reasonable expectation of success in view of Wolff's teaching and the prior art teachings.

***Objections Specification - Abstract***

Applicant is reminded of the proper content of an abstract of the disclosure.

With regard particularly to chemical patents, for compounds or compositions, the general nature of the compound or composition should be given as well as the use thereof, e.g., *The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics.* Exemplification of a species could be illustrative of members of the class. For processes, the reaction type, reagents and process conditions should be stated, generally illustrated by a single example, unless variations are necessary. See MPEP § 608.01(b), Section B.

The abstract of the disclosure is objected to because: a) it neither provides for the general nature of the compounds nor exemplifies any members or formulae

illustrative of its class; and b) should be amended to reflect the scope of the *Requirement for Restriction / Election of Species*, mailed on April 1, 2009. Correction is required. See MPEP § 608.01(b).

### ***Specification Objection - Title***

Applicant is reminded of the proper content of the title of the invention.

The title of the invention should be brief, but technically accurate and descriptive, preferably from two to seven words. See 37 CFR 1.72(a) and MPEP § 606.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In the revised title, the examiner suggests including the name of the main core of the chemical structure and the alleged utility possessed by the compounds applicants regard as their invention.

### ***Claim Objections***

9. Claims 7-9 are objected to because of the following informalities: Independent claim 1 should start with the article, --A--, and dependent claims should start with --The--. Appropriate correction is required.

10. Claims 7-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 recites exactly the same as claim 6 and "may be bound to...". However, "maybe bound to..." does not further limit claim 6. Claim 9 recites a "compound comprising a polyamido

moiety" which is similar to "a polyamido moiety comprising" of claim 6. No limitations have been added to claim 9 to further limit parent claim 6.

11. Claims 6-9 and 23 are objected to as containing non-elected subject matter.

Claims 6-9 and 23 presented drawn solely to the elected invention identified supra as **the elected invention for search and examination** would overcome this objection.

**Telephone Inquiry**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/  
Primary Examiner, Art Unit 1626

/VALERIE RODRIGUEZ-GARCIA/  
Art Unit 1626